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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HAND, MELANIE JO

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,574	Applicant(s) SIGURJONSSON ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-16, 18-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-16, 18-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 12, 14-16, 18-20 and 22 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's submission of an information disclosure statement.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 23, 2008 was filed after the mailing date of the non-final action on February 14, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 12, 14-16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Lawry (U.S. Patent Application Publication No. 2002/0156410).

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With respect to **claim 12**: Lawry discloses a wound dressing 10 having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface. (Fig. 3, ¶0030) The dressing 10 comprises an absorbent core in the form of gauze pad 14 defining opposed proximal and distal surfaces. (¶0030) The distal surface includes a central portion and a border portion adjacent the periphery of the layer. The dressing also comprises a liquid impervious, vapor permeable backing layer 12 (inasmuch as it is constructed from plastic sheet material) defining opposed proximal and distal surfaces. The proximal surface of the backing layer 12 extends over the distal surface of the absorbent core 14 (Fig. 1) and defines a border portion extending beyond and surrounding peripheral edges of the absorbent core 14. The distal surface of the backing layer 12 defines the backside surface of the wound dressing 10. (Fig. 2) A first skin adherent facing layer 26 is directly secured only to the proximal surface of the border portion of the backing layer 12 beyond the peripheral edges of core 14 and surrounds the peripheral edges of the absorbent core. (¶0033) A proximal surface of the first facing layer 26 defines a portion of the bodyside surface of the wound dressing 10. (Fig. 2) A facing layer in the form of gel layer 16 is bonded to and coextensive with the proximal surface of the absorbent core 14 (Fig. 2, ¶¶0033,0040). A proximal surface of the second facing layer 16 defines a portion of the bodyside surface of the wound dressing and is considered herein to be generally co-planar with the proximal surface of the first facing layer 26 inasmuch as “generally coplanar” is defined synonymously in applicant’s disclosure with “generally planar”. Since the

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term “generally planar” is also not clearly or explicitly defined in applicant's disclosure, the claim is given its broadest reasonable interpretation, i.e. a proximal surface of the second facing layer 16 is considered generally coplanar with the first facing layer because they are approximately coplanar. A periphery of the second facing layer 16 is contiguous with a periphery of the first facing layer (Fig. 1) inasmuch as the periphery of the first facing layer is defined by the periphery of the absorbent core because the first facing layer is only present in said border portion of the backsheet proximal surface. Since the second facing layer 16 is coextensive with the core, its periphery is also defined by the core periphery and thus the periphery of the first facing layer and second facing layer are contiguous. The core is pre-impregnated with the silicone gel adhesive forming layer 16 (¶0012) and thus the layer 16 will necessarily have apertures where the gauze has apertures. Since gauze by its nature defines a grid pattern of through-extending apertures, the second facing layer 16 will also define a grid pattern of through extending apertures arranged across the second facing layer and non-apertured regions surrounding the apertures. The bodyside surface of the wound dressing 10 consists of the proximal

surfaces of the first and second facing layers 26,16 respectively. (Fig. 2, layer 26 not shown, ¶0033) The second facing layer 16 is composed of a skin adherent hydrophobic silicone gel compound. (¶¶0037,0038) The thickness of the non-apertured regions necessarily consist of the silicone gel compound as it is the silicone gel layer that defines the grid pattern of apertured and non-apertured regions, thus the non-apertured regions are the only areas where the silicone gel compound of the gel layer 16 is present.

With respect to **claim 14**: The border portion of the backing layer 12 is substantially parallel with the distal surface of the absorbent core 14. (Fig. 2)

With respect to **claim 15**: The border portion of the backing layer 12 includes at least two opposed elongate sections, each opposed elongate section extending from a corresponding side of the absorbent core 14. (Figs. 1,2)

With respect to **claim 16**: The first facing layer 26 is a pressure sensitive adhesive. (¶0038)

With respect to **claim 18**: Applicant has not explicitly and clearly defined the phrase “sufficiently porous”, thus the claim is given its broadest reasonable interpretation. Since Lawry discloses a pressure-sensitive adhesive, which is also disclosed and claimed by applicant, the first facing layer of Lawry is considered herein to also be sufficiently porous so as not to occlude moisture transmission through the backing layer.

With respect to **claim 19**: Lawry discloses that the silicone gel of the second facing layer has greater wettability than glues typically used for securement of dressings and prevents bacteria from forming, and increased wettability necessarily leads to lesser skin adherence capability or property. It is examiner's position that the pressure-sensitive adhesive disclosed by applicant for the claimed first facing layer, and Lawry for the instant first facing layer, is a glue that is typically used for securement of dressings. Therefore, while Lawry does not explicitly disclose that the first facing layer of pressure sensitive adhesive has greater skin adherence properties than the second facing layer of silicone gel, it would be obvious to one of ordinary skill in the art to modify the article of Lawry such that the first facing layer has the greater skin adherence property to ensure that the dressing stays in place during wear while allowing the desired wettability of the second facing layer to prevent bacteria formation.

With respect to **claim 20**: Lawry discloses in an alternate embodiment in Fig. 4 an absorbent core 14 wherein the peripheral edges of the absorbent core have a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof. Since Lawry discloses that both the unbeveled core in Fig. 2 and the beveled core in Fig. 4 are equally effective for providing a dressing for burn wounds, it would be obvious to one of ordinary skill in the art to modify the dressing of Fig. 2 such that the peripheral edges of the absorbent core have a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawry ('410).

With respect to **claim 22**: Lawry discloses a wound dressing 10 having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface. (Fig. 3, ¶0030) The dressing 10 comprises an absorbent core in the form of gauze pad 14 defining opposed proximal and distal surfaces. (¶0030) The distal surface includes a central portion and a border portion adjacent the periphery of the layer. The dressing also comprises a liquid impervious, vapor permeable backing layer 12 (inasmuch as it is constructed from plastic sheet material) defining opposed proximal and distal surfaces. The proximal surface of the backing layer 12 extends over the distal surface of the absorbent core 14 (Fig. 1) and defines a border portion extending beyond and surrounding peripheral edges of the absorbent core 14. The distal surface of the backing layer 12 defines the backside surface of the wound dressing 10. (Fig. 2) A first skin adherent facing layer 26 is directly secured only to the proximal surface of the border portion of the backing layer 12 beyond the peripheral edges of core 14 and surrounds the peripheral edges of the absorbent core. (¶0033) A proximal surface of the first facing layer 26 defines a portion of the bodyside surface of the wound dressing 10. (Fig. 2) A facing layer in the form of gel layer 16 is bonded to and coextensive with the proximal surface of the absorbent core 14 (Fig. 2, ¶¶0033,0040). A proximal surface of the second facing layer 16 defines a portion of the bodyside surface of the wound dressing and is considered herein to be generally co-planar with the proximal surface of the first facing layer 26 inasmuch as “generally coplanar” is defined synonymously in applicant’s disclosure with “generally planar”. Since the term “generally planar” is also not clearly or explicitly defined in applicant’s disclosure, the claim is given its broadest reasonable interpretation, i.e. a proximal surface of the second facing layer 16 is considered generally coplanar with the first facing layer

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because they are approximately coplanar. A periphery of the second facing layer 16 is contiguous with a periphery of the first facing layer (Fig. 1) inasmuch as the periphery of the first facing layer is defined by the periphery of the absorbent core because the first facing layer is only present in said border portion of the backsheet proximal surface. Since the second facing layer 16 is coextensive with the core, its periphery is also defined by the core periphery and thus the periphery of the first facing layer and second facing layer are contiguous. The core is pre-impregnated with the silicone gel adhesive forming layer 16 (¶0012) and thus the layer 16 will necessarily have apertures where the gauze has apertures. Since gauze by its nature defines a grid pattern of through-extending apertures, the second facing layer 16 will also define a grid pattern of through extending apertures arranged across the second facing layer and non-apertured regions surrounding the apertures. The bodyside surface of the wound dressing 10 consists of the proximal surfaces of the first and second facing layers 26,16 respectively. (Fig. 2, layer 26 not shown, ¶0033) The second facing layer 16 is composed of a skin adherent hydrophobic silicone gel compound. (¶¶0037,0038) The thickness of the non-apertured regions necessarily consist of the silicone gel compound as it is the silicone gel layer that defines the grid pattern of apertured and non-apertured regions, thus the non-apertured regions are the only areas where the silicone gel compound of the gel layer 16 is present.

Lawry discloses that the gauze of core 14 is impregnated with the silicone gel forming the second facing layer. Therefore the apertures in the second facing layer are not formed irrespective of the proximal surface of the core. However, an article in which the grid pattern of apertures are formed irrespective of the proximal surface of the absorbent core would yield an article that is substantially identical to that disclosed. Therefore it would be obvious to one of ordinary skill in the art to modify the article of Lawry such that the grid pattern of apertures in the second facing layer are formed irrespective of the proximal surface of the absorbent core with a

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reasonable expectation of success to provide an article that functions as intended. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawry (‘410) in view of de Jong et al (U.S. Patent Application Publication No. 2003/0120229).

With respect to **claim 23**: Lawry discloses a wound dressing 10 having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface. (Fig. 3, ¶0030) The dressing 10 comprises an absorbent core in the form of gauze pad 14 defining opposed proximal and distal surfaces. (¶0030) The distal surface includes a central portion and a border portion adjacent the periphery of the layer. The dressing also comprises a liquid impervious, vapor permeable backing layer 12 (inasmuch as it is constructed from plastic sheet material) defining opposed proximal and distal surfaces. The proximal surface of the backing layer 12 extends over the distal surface of the absorbent core 14 (Fig. 1) and defines a border portion extending beyond and surrounding peripheral edges of the absorbent core 14. The distal surface of the backing layer 12 defines the backside surface of the wound dressing 10. (Fig. 2) A first skin adherent facing layer 26 is directly secured only to

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the proximal surface of the border portion of the backing layer 12 beyond the peripheral edges of core 14 and surrounds the peripheral edges of the absorbent core. (¶0033) A proximal surface of the first facing layer 26 defines a portion of the bodyside surface of the wound dressing 10. (Fig. 2) A facing layer in the form of gel layer 16 is bonded to and coextensive with the proximal surface of the absorbent core 14 (Fig. 2, ¶¶0033,0040). A proximal surface of the second facing layer 16 defines a portion of the bodyside surface of the wound dressing and is considered herein to be generally co-planar with the proximal surface of the first facing layer 26 inasmuch as “generally coplanar” is defined synonymously in applicant’s disclosure with “generally planar”. Since the term “generally planar” is also not clearly or explicitly defined in applicant’s disclosure, the claim is given its broadest reasonable interpretation, i.e. a proximal surface of the second facing layer 16 is considered generally coplanar with the first facing layer because they are approximately coplanar. A periphery of the second facing layer 16 is contiguous with a periphery of the first facing layer (Fig. 1) inasmuch as the periphery of the first facing layer is defined by the periphery of the absorbent core because the first facing layer is only present in said border portion of the backsheet proximal surface. Since the second facing layer 16 is coextensive with the core, its periphery is also defined by the core periphery and thus the periphery of the first facing layer and second facing layer are contiguous. The core is pre-impregnated with the silicone gel adhesive forming layer 16 (¶0012) and thus the layer 16 will necessarily have apertures where the gauze has apertures. Since gauze by its nature defines a grid pattern of through-extending apertures, the second facing layer 16 will also define a grid pattern of through extending apertures arranged across the second facing layer and non-apertured regions surrounding the apertures. The bodyside surface of the wound dressing 10 consists of the proximal surfaces of the first and second facing layers 26,16 respectively. (Fig. 2, layer 26 not shown, ¶0033) The second facing layer 16 is composed of a skin adherent

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hydrophobic silicone gel compound. (¶¶0037,0038) The thickness of the non-apertured regions necessarily consist of the silicone gel compound as it is the silicone gel layer that defines the grid pattern of apertured and non-apertured regions, thus the non-apertured regions are the only areas where the silicone gel compound of the gel layer 16 is present.

Lawry discloses that the gauze of core 14 is impregnated with the silicone gel forming the second facing layer. Therefore the apertures in the second facing layer are not formed irrespective of the proximal surface of the core. However, an article in which the grid pattern of apertures are formed irrespective of the proximal surface of the absorbent core would yield an article that is substantially identical to that disclosed. Therefore it would be obvious to one of ordinary skill in the art to modify the article of Lawry such that the grid pattern of apertures in the second facing layer are formed irrespective of the proximal surface of the absorbent core with a reasonable expectation of success to provide an article that functions as intended. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

Lawry does not teach a polymeric foam-based absorbent core. However the use of such polymeric foams as absorbent core materials is well known in the art of wound dressings as supported by de Jong (‘229, ¶0007), therefore it would be obvious to one of ordinary skill in the art to modify the wound dressing of Lawry such that the dressing is comprised of a polymeric

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foam based absorbent core with a reasonable expectation of success to ensure that the wound dressing aptly provides the function of absorbing wound exudates.

Conclusion

9. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on July 23, 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761